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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,695	06/10/2005	Jin Woo Park	11617-004	6982
20583	7590	07/27/2007		
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			EXAMINER AHMED, HASAN SYED	
			ART UNIT	PAPER NUMBER
			1615	
			MAIL DATE	DELIVERY MODE
			07/27/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/538,695	Applicant(s) PARK ET AL.	
	Examiner Hasan S. Ahmed	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 8-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

Receipt is acknowledged of applicants' response (filed on 25 April 2007).

\* \* \* \* \*

#### *Priority*

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

\* \* \* \* \*

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kikuchi et al. (US 2004/0022848).

Kikuchi et al. teach a pharmaceutical preparation obtained by primary granulation of a drug and a hydrophobic additive (waxy substance) (see paragraphs 0061 and 0062), followed by secondary granulation of the obtained granules by wet granulation using a hydrophobic wet granulation material (see paragraph 0065).

Kikuchi et al. explain that this technique is beneficial in taste masking (see paragraph 0066).

The Kikuchi et al. reference differs from the instant application in that it does not teach a melt granulation technique for primary granulation. However, the granulation

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techniques are not essential to a determination of patentability of the composition disclosed in the claim. As explained by the court in *In re Thorpe et. al.* (CAFC 1985) 779 F2d 695, "A claim to a composition defined by reference to the process by which it is produced, is not limited to compositions produced by the process recited in the claim."

Furthermore, although Kikuchi et al. do not explicitly teach a sustained release preparation, properties are the same when the structure and composition are the same. Here, the instant application and the prior art both disclose a primary granulation product containing a hydrophobic additive which is subject to secondary granulation with a hydrophobic wet granulation material. Thus, burden shifts to applicant to show unexpected results, by declaration or otherwise. *In re Fitzgerald*, 205 USPQ 594. In the alternative, the claimed properties would have been present once the composition was employed in its intended use. *In re Best*, 195 USPQ 433.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a pharmaceutical preparation obtained by primary granulation of a drug followed by secondary granulation of the granules obtained from primary granulation, as taught by Kikuchi, et. al. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it is useful in taste masking, as explained by Kikuchi, et. al.

\*

2. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kikuchi et al. (US 2004/0022848) in view of Oshlack et al. (US 2002/0102302).

Kikuchi et al. teach a pharmaceutical preparation (see above). The Kikuchi et al. reference differs from the instant application in that it does not teach the specific drug and excipients claimed.

Oshlack et al. teach a sustained release composition (see paragraph 0014) comprising:

- the tramadol of instant claim 3 (see paragraph 0014);
- the waxes of instant claim 4 (see paragraph 0056);
- the beeswax of instant claim 5 (see paragraph 0056);
- the hydrogenated vegetable oil of instant claim 6 (see paragraph 0056); and
- the additives of instant claim 7 (see paragraph 0021).

Oshlack et al. explain that the combination of these ingredients into one preparation is beneficial for the sustained treatment of pain (see paragraph 0013).

While Oshlack et al. do not explicitly teach all the percentages of instant claim 2, examiner respectfully submits that it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955).

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Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage ranges.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a sustained release pharmaceutical preparation comprising tramadol and using two granulation processes, as taught by Kikuchi et al. in view of Oshlack et al. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it is useful in the sustained treatment of pain, as explained by Oshlack, et. al.

\* \* \* \* \*

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 11/572,326 ('326). Although the conflicting claims are not identical, they are not patentably distinct from each other because '326 claims a sustained release pharmaceutical composition prepared by a first granulation method followed by a second granulation method.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

\* \* \* \* \*

### ***Response to Arguments***

Applicants' arguments filed on 25 April 2007 have been fully considered but they are not persuasive.

### **35 USC 103 (Kikuchi)**

1. Applicants argue that the Kikuchi reference does not teach wet granulation as a secondary granulation with hydrophobic materials. See remarks, page 3.

Examiner respectfully disagrees. The Kikuchi reference states, "[s]econdary granulation may be accomplished by wet fluidized bed granulation..." See paragraph 0065, emphasis supplied. Furthermore, Kikuchi teaches the preparation in a waxy (hydrophobic) material (see paragraph 0066).

In any event, examiner respectfully submits that the processes of primary and secondary granulation disclosed in claim 1 are not essential to a determination of patentability of the composition disclosed in the claim. The patentability of product-by-

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process claims is based on the product itself. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

\*

2. Applicants argue that, "...the technical solution used in Kikuchi is 'to add synthetic aluminum silicate and hydrous silicon dioxide, but not 'secondary granulation' as in the present invention." See remarks, page 4, first paragraph.

Examiner respectfully submits that Kikuchi teaches secondary granulation, as claimed in the instant application (see above). Additionally, a difference in objectives between the instant application and the prior art, if any, does not defeat the case for obviousness because, as MPEP § 2144 states, the "reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. In re Linter, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972) ...; In re Dillon, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991) ... ."

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3. Directing the record to Example 2 of Kikuchi, applicants argue that Kikuchi does not teach or suggest a sustained-release preparation. See remarks, page 4, second full-paragraph.

The recitation "sustained-release" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Alternatively, examiner respectfully submits that the instant application does not provide a definition of "sustained-release." Thus, reading said phrase in light of its broadest reasonable interpretation, examiner respectfully submits that the Kikuchi invention is within the scope of the instant application. Kikuchi teaches a formulation comprising a waxy substance (see, e.g., paragraphs 0056 and 0066) and other excipients (see paragraph 0068) known to be used in sustained-release formulations (see paragraph 0002).

Addressing Example 2 of Kikuchi, the applicants' argument is based on what the examiner believes to be a narrow interpretation of the prior art. A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including non-preferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). It is the

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position of the examiner that one of ordinary skill in the art, given both the prior art and the claims in their present form their broadest reasonable interpretation, would find the claimed invention obvious in view of the prior art. See MPEP § 2111 and 2123.

\*

**35 USC 103 (Kikuchi in view of Oshlack)**

Applicants argue that, "...Oshlack fails to teach or suggest essential elements of wet granulation using hydrophobic material in the claimed invention." See remarks, page 5.

Examiner respectfully submits that the primary reference, Kikuchi, was relied upon to teach said limitation.

Furthermore, as explained above, the processes of primary and secondary granulation are not essential to a determination of patentability of the composition disclosed in the claim. The patentability of product-by-process claims is based on the product itself. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

\* \* \* \* \*

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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***Correspondence***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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HUMERA N. SHEIKH  
PRIMARY EXAMINER